

D.J.

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Michelle P. Chicos

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Robert N. McBurney et al.

Art Unit:

Serial No.:

09/530,884

Examiner:

Filed:

May 5, 2000

Title:

THERAPEUTIC METHODS COMPRISING USE OF A

NEUREGULIN

Assistant Commissioner For Patents Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the attached form PTO 1449, copies of which are enclosed.

Submission of this statement is not a representation that a search has been made nor is information included in this statement an admission that the information is material to patentability.



This statement is being filed before the receipt of a first Office action on the

merits. Please apply any charges or credits to Deposit Account 03-2095.

Respectfully submitted,

Kristina Bieker-Brady Reg. No. 39,109

Clark & Elbing LLP 176 Federal Street Boston, MA 02110

Telephone: 617-428-0200

Facsimile: 617-428-7045

Sheet 2 of 4 SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE Attorney Docket No. 04585/048002 PATENT AND TRADEMARK OFFICE (MODIFIED) Serial No. 09/530,884 INFORMATION DISCLOSURE Applicant Robert N. McBurney et al. STATEMENT BY APPLICANT (Use several sheets if necessary) Filing Date May 5, 2000 (37 CFR §1.98(b)) Group **IDS Filed** October 19, 2000 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Brockes et al., "The neuron as a source of mitogen: its influence on the proliferation of glial and non-neural cells." In Development in the Nervous System, Garrod and Feldman, pp 309-327 (1980). Canoll et al., "GGF/Neuregulin is a Neuronal Signal that Promotes the Proliferation and Survival and Inhibits the Differentiation of Oligodendrocyte Progenitors." Neuron 17:229-243 (1996). Cheema et al., "Leukemia Inhibitory Factor Prevents the Death of Axotomised Sensory Neurons in the Dorsal Root Ganglia of the Neonatal Rat." J. Neurosci. Res. 37:213-218 (1994). Chen et al., "Expression of Multiple Neuregulin Transcripts in Postnatal Rat Brains." J. Comp. Neurol. 349:389-400 (1994). Curtis et al., "Retrograde axonal transport of cillary neurotrophic factor is increased by peripheral nerve injury." Nature 365:253-255 (1993). Curtis et al., "Retrograde Axonal Transport of LIF is increased by Peripheral Nerve Injury: Correlation with Increased LIF Expression in Distal Nerve." Neuron 12:191-204 (1994). Danilenko et al., "Neu Differentiation Factor (NDF) Accelerates Epidermal Migration and Differentiation in Excisional Wounds." Faseb J. 8(4-5) A535 (1994). Davis & Stroobant, "Platelet-derived Growth Factors and Fibroblast Growth Factors are Mitogens for Rat Schwann Cells." J. Cell Biol. 110:1353-1360 (1990). Davis et al., "Isolation and characterization of a neu protein-specific activating factor from human ATL-2 cell conditioned medium." Biochem. Biophys. Res. Commun. 179:1536-1542 (1991). Dobashi et al., "Characterization of a neu/c-erbB-2 protein-specific activating factor." Proc. Natl. Acad. Sci. USA 88:8582-8586 (1991). Falls et al., "ARIA, a Protein that Stimulates Acetylcholine Receptor Synthesis, is a Member of the Neu Ligand Family." Cell 72:801-815 (1993). Falls et al., "M,42,000 ARIA: A Protein that may Regulate the Accumulation of Acetylcholine Receptors at Developing Chick Neuromuscular Junctions." Cold Spring Harb. Symp. Quant. Biol. 55:397-406 (1990). Fann et al., "A Novel Approach to Screen for Cytokine Effects on Neuronal Gene Expression." J. Neurochem. 61:1349-1355 (1993). Funakoshi et al., "Differential Expression of mRNAs for Neurotrophins and their Receptors after Axotomy of the Sciatic Nerve." J. Cell Biol. 123:455-465 (1993). Grinspan et al., "Axonal Interactions Regulate Schwann Cell Apoptosis in Developing Peripheral Nerve: Neuregulin Receptors and the Role of Neuregulins." J. Neurosci. 16:6107-18 (1996). Harris et al., "A prion-like protein from chicken brain copurifies with an acetylcholine receptor-inducing activity." Proc. Natl. Acad. Sci. USA 88:7664-7668 (1991). **EXAMINER** DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

Sheet 1 of 4 SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE Attorney Docket No. 04585/048002 PATENT AND TRADEMARK OFFICE (MODIFIED) 09/530,884 Serial No. Robert N. McBurney et al. INFORMATION DISCLOSURE Applicant STATEMENT BY APPLICANT Filing Date May 5, 2000 (Use several sheets if necessary) (37 CFR §1.98(b)) Group **IDS Filed** October 19, 2000 U.S. PATENTS Patent Number Issue Date Patentee Class Subclass Filing Date Examiner's (If Appropriate) Initials 5,082,670 01/21/92 Gage et al. 5,399,346 03/21/95 Anderson et al. 5,367,060 11/22/94 Vandlen et al. 5,237,056 08/17/93 Fischbach et al. 5,602,096 02/11/97 Goodearl et al. 5,530,109 06/25/96 Goodearl et al. FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION Subclass Translation Class Document Publication Country or (Yes/No) Number Patent Office Date 11/26/92 PCT WO 92/20798 EP 0 505 148 09/23/92 Europe **A1** WO 92/12174 07/23/92 **PCT** WO 91/18921 12/12/91 PCT WO 91/15230 10/17/91 PCT WO 94/00140 01/06/94 PCT WO 94/04560 03/03/94 PCT WO 94/08007 04/14/94 PCT WO 94/03644 02/17/94 PCT OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) Acsadi et al., "Human dystrophin expression in mdx mice after intramuscular injection of DNA constructs." Nature 352:815-818 (1991). Benveniste et al., "Purification and characterization of a human T-lymphocyte-derived glial growth-promoting factor." Proc. Natl. Acad. Sci. USA 82:3930-3934 (1985). Brockes et al., "Assay and Isolation of Glial Growth Factor from the Bovine Pituitary." Meth. Enz. 147:217-225 DATE CONSIDERED **EXAMINER**

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

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	FORM PTO-1449 U.S. DEPARTMENT OF COM		Attorney Docket No.	04585/048002			
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	INFORMATION DISCLOSURE		Applicant	Robert N. McBurney et al.			
STATEMENT BY APPLICANT (Use several sheets if necessary) . (37 CFR §1.98(b))			Filing Date	May 5, 2000			
			Group				
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	OTHER DOCUMENTS (INCLUDING AUTHOR,	TITLE, D					
	Hefti, "Neurotrophic Factor Therapy for Nervous S (1994).		· · · · · · · · · · · · · · · · · · ·				
	Henderson et al., "GDNF: A Potent Survival Facto Science 266:1062-1064 (1994).	or for Motor	neurons Present in Peri	pheral Nerve and Muscle."			
	Holmes et al., "Identification of Heregulin, a Specific Activator of p185erbB2." Science 256:1205-1210 (1992).						
	Huang et al., "Purification and Characterization of the neu/erb B2 Ligand-Growth Factor from Bovine Kidney." J. Biol. Chem. 267:11508-11512 (1992).						
	Hughes et al., "Members of Several Gene Families Influence Survival of Rat Motoneurons In Vitro and In Vivo J. Neurosci. Res. 36:663-671 (1993).						
	Kimura et al., "Structure, expression and function of a schwannoma-derived growth factor." <i>Nature</i> 348:257-260 (1990).						
	Kotzbauer et al., "Postnatal Development of Survival Responsiveness in Rat Sympathetic Neurons to Leukem Inhibitory Factor and Ciliary Neurotrophic Factor." <i>Neuron</i> 12:763-773 (1994).						
	Lillien & Raff, "Differentiation Signals in the CNS: Type 2 Astrocyte Development In Vitro as a Model System." Neuron 5:111-119 (1990).						
	Lin et al., "GDNF: A Glial Cell Line-Derived neurotrophic Factor for Midbrain Dopaminergic Neurons." Science 260:1130-1132 (1993).						
	Lupu et al., "Direct Interaction of a Ligand for the <i>erb</i> B2 Oncogene Product with the EGF Receptor and p ^{185erbB2} " Science 249:1552-55 (1990).						
	Lupu et al., "Characterization of a growth factor that binds exclusively to the <i>erb</i> B-2 receptor and induces cellular responses." <i>Proc. Natl. Acad. Sci. USA</i> 89:2287-2291 (1992).						
	Mahanthappa et al., "Glial Growth Factor 2, a Soluble Neuregulin, Directly Increases Schwann Cell Motility and Indirectly Promotes Neurite Outgrowth." <i>J. Neurosci.</i> 16:4673-4683 (1996).						
	Marchionni et al., "Glial growth factors are alternatively spliced erbB2 ligands expressed in the nervous system." Nature 362:312-318 (1993).						
	Martinou et al., "Cholinergic Differentiation Factor (CDF/LIF) Promotes Survival of Isolated Rat Embryonic Motoneurons In Vitro." Neuron 8:737-744 (1992).						
	Mitsumoto et al., "Arrest of Motor Neuron Disease in wobbler Mice Cotreated with CNTF and BDNF." Science 265:1107-1110 (1994).						
	Mudge, "New ligands for Neu?" Current Biol. 3:361-64 (1993).						
	Nishi, "Neurotrophic Factors: Two are Better than One." Science 265:1052-53 (1994).						
	Oppenheim et al., "Developing motor neurons rescued from programmed and axotomy-induced cell death by GDNF." Nature 373:344-346 (1995).						
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			IDS Filed	October 19, 2000	
	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)				
	Peles & Yarden, "Neu and its Ligands: From an Oncogene to Neural Factors." Bio Essays 15:815-82				
	Peles et al., "Isolation of the Neu/HER-2 Stimulatory Ligand: A 44kd Glycoprotein that Induces Different Mammary Tumor Cells." Cell 69:205-216 (1992).				
	Pinkas-Kramarski, "Brain neurons and glial cells express Neu differentiation factor/heregulin: A surviva for astrocytes." <i>Proc. Natl. Acad. Sci. USA</i> 91:9387-9391 (1994).				
	Rosenbaum et al., "Schwann Cells Express NDF and SMDF/n-ARIA mRNAs, Secrete Neuregulin, and Constitutive Activation of erbB3 Receptors: Evidence for a Neuregulin Autocrine Loop." Ex. Neurol. 14 615 (1997).				
	Syroid et al., "Cell death in the Schwann cell lineage and its regulation by neuregulin." <i>Proc. Natl. Acad USA</i> 93:9229-9234 (1996).				
	Trachtenberg et al., "Schwann cell apoptosis at developing neuromuscular junctions is regulated by gli factor." Nature 379:174-177 (1996).				
	Usdin & Fischbach, "Purification and Characterization of a Polypeptide from Chick Brain that Promotes Accumulation of Acetylcholine Receptors in Chick Myotubes." <i>J. Cell Biol.</i> 103:493-507 (1986).				
	Verdi et al., "A Reciprocal Cell-Cell Interaction Mediated by NT-3 and Neuregulins Controls the Early Stand Development of Sympathetic Neuroblasts." Neuron 16:515-527 (1996).				
	Wen et al., "Neu Differentiation Factor: A Transmembrane Glycoprotein Containing an EGF Domain an Immunoglobulin Homology Unit." <i>Cell</i> 69:559-572 (1992).				
	Wolswijk, "Chronic Stage Multiple Sclerosis Lesions Contain a Relatively quiescent Population of Oligodendrocyte Precursor Cells." <i>J. Neurosci.</i> 18:601-609 (1998).				
	Xie et al., "Rapid, Small-Scale RNA Isolation from Tissue Culture Cells." Biotechniques 11:325-327 (19				
-	Yamamori et al., The Cholinergic Neuronal Differentiation Factor from Heart Cells is Identical to Leuken Inhibitory Factor." Science 246:1412-1416 (1989).				
	Yan et al., "In vivo neurotrophic effects of GDNF on neonatal and adult facial motor neurons." Nature 3: 344 (1995).				
	Yarden & Ullrich, "Growth Factor Receptor Tyrosine Kinases." Annu. Rev. Bioch. 57:443-478 (1988).				
	Yarden & Peles, "Biochemical Analysis of the Ligand for the <i>neu</i> Oncogenic Receptor." <i>Biochemistry</i> 30 3550 (1991).				
	Yuen et al., "Therapeutic Potential of Neurotrophic Factors for Neurological Disorders." Ann. Neurol. 40 354 (1996).				
	Yin et al., "Cell Death of Spinal Motoneurons in the Chick Embryo following Deafferentation: Rescue Effe Tissue Extracts, Soluble Proteins, and Neurotrophic Agents." <i>J. Neurosci.</i> 14:7629-7640 (1994).				
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